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Commissioner for Patents
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Sir:

This Brief is submitted on appeal under 35 U.S.C. § 134 from the Final Rejection in the Office Action dated August 24, 2006, of claims 1-6, 15, 19, and 22 of U.S. Patent Application No. 10/049,404. A Notice of Appeal was filed January 24, 2007. The two month appeal brief submission deadline from such Notice of Appeal filing date is March 24, 2007. This Appeal Brief therefore is timely.

The appeal brief fee of \$250.00 for small entity specified in 37 C.F.R. 41.20 (b)(2) is enclosed in the form of a Credit Card Payment Form directing charging of such amount to the credit card identified in such Form.

Authorization also is hereby given, to charge any additional fee or amount properly payable in connection with the filing of this Appeal Brief, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

No oral hearing is requested.

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REAL PARTY IN INTEREST

The real party in interest in this appeal is Deutsche's Krebsforschungszentrum Stiftung des Offentlichen Rechts, the owner of the invention and patent rights of this application, by virtue of an Assignment recorded in the assignment records of the U.S. Patent and Trademark Office on August 5, 2002 at reel/frame 013155/0367 (3 pages).

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to appellant, the appellant's legal representative, or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1-22 are pending in the subject application; no claims have been allowed; claims 1-6, 15, 19, and 22 have been rejected and claims 7-14, 16-18, 20 and 21 are withdrawn.

In the August 24, 2006 Office Action, claim 22 was finally rejected under 35 U.S.C. §112, first and second paragraphs, claims 1-6, 19, 19, and 22 were rejected under 35 U.S.C. §112, first paragraph, claims 1-6, 15, 19, and 22 were rejected under 35 U.S.C. §102(a) as anticipated by Arndt et al., *Blood*, 94; 8:2562-2568 (1999), claims 1-5, and 15 were finally rejected under 35 U.S.C. §102(b) as being anticipated by Hartmann et al., *Blood*, 89; 6:2042-2047 (1997), and claims 1-6, 15, 19 and 22 were finally rejected under

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35 U.S.C. §103(a) as being obvious over Hartmann et al., *Leukemia and Lymphoma*, 31:385-392 (1998), in view of Hollinger et al., *PNAS*, 93:6444-6448 (1993).

The rejections of claims 1-6, 19, 19, and 22 under 35 U.S.C. §112, first paragraph, and claims 1-6, 15, 19, and 22 under 35 U.S.C. §102(a) as anticipated by Arndt et al. were withdrawn by the examiner in the Advisory Action mailed November 7, 2007. The remaining rejections were maintained in the Advisory Actions mailed November 7, 2006 and February 6, 2007.

Thus the rejections of record that constitute the subject of this Appeal are the 35 U.S.C. § 112, first and second paragraphs rejections of claim 22, the 35 U.S.C. §102(b) rejection of claims 1-5, and 15, and the 35 U.S.C. §103(a) rejection of claims 1-6, 15, 19 and 22.

A copy of the appealed claims 1-6, 15, 19 and 22 is attached in Claims Appendix hereof.

STATUS OF AMENDMENTS

In the response mailed January 24, 2007, submitted after the Final Office Action of August 24, 2006, applicants submitted an amendment to claim 22. The amendment was not entered.

The claims 1-22 in the Claims Appendix are the claims to which the August 24, 2006 Final Office Action was directed.

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SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to an F_v antibody construct having variable domains for CD16 and CD30 but no constant domains and where the construct induces a regression of Hodgkin's disease *in vivo*. Such an F_v construct is described in detail throughout the specification, in particular at page 2, lines 19-22, page 3, lines 9-14, and is constructed in Example 1 and illustrated in Figure 1. *In vivo* efficacy of the construct is demonstrated in Example 3(C) as against Hodgkin's lymphomas in mice.

GROUND S OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are to be reviewed in this appeal:

- (a) Whether claim 22 is indefinite under the definition of 35 U.S.C. § 112, second paragraph.
- (b) Whether claim 22 fails to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph.
- (c) Whether claims 1-5, and 15 are unpatentable under 35 U.S.C. §102(b) in view of Hartmann et al., *Blood*, 89; 6:2042-2047 (1997).
- (d) Whether claims 1-6, 15, 19 and 22 are unpatentable under 35 U.S.C. §103(a) over Hartmann et al., *Leukemia and Lymphoma*, 31:385-392 (1998), in view of Hollinger et al., *PNAS*, 93:6444-6448 (1993).

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ARGUMENT

(a) Claim 22 is definite under 35 U.S.C. § 112, second paragraph

Claim 22 was added by the applicants in the Office Action response submitted on June 13, 2006. Support for such claim is found in the specification in Example 3(B) of the specification, particularly at page 10, lines 24-27.

In the Final Office Action mailed August 24, 2006, the examiner rejected claim 22 as indefinite for failing to particularly point out and distinctly claim the subject matter of the in the invention, as the claim was alleged to be “indefinite in the recitation of ‘a more intense lysis.’” Specifically, the examiner stated that (1) “[t]he phrase is not defined by the claim, [(2)] the specification does not provide a standard for ascertaining the requisite degree, and [(3)] one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.” (Final Office Action mailed August 24, 2006, p. 3.) Applicants disagree with all of the examiner’s allegations.

Definition of the term in the claim

Initially, it is noted that the complete phrase of claim 22 that should be considered is not just “a more intense lysis,” but “inducing a more intense lysis of CD30 carrying cells *in vitro* than bimAbHRS-3/A9 (DSM ACC 2142)” (emphasis added). Accordingly, the standard for the term in question is the lysis intensity of CD30 carrying cells *in vitro* by bimAbHRS-3/A9 (DSM ACC 2142), a standard against which the F_v antibody construct of claim 1 is compared. Therefore, the term “a more intense lysis” is defined in

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the body of the claim, as compared with the lysis of CD30 cells *in vitro* induced by bimAbHRS-3/A9.

bimAbHRS-3/A9 is a known and publicly available bispecific monoclonal antibody, which has been deposited with Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ), a recognized International Depositary Authority for the deposit of biological material under the Budapest Treaty, as indicated by the Accession number DSM ACC2142 included in the claim language.

As such, the claim clearly defines “a more intense lysis” as lysis by an F_v construct of the invention in comparison with lysis by bimAbHRS-3/A9.

Definition of the term in the specification

Furthermore, comparison of the lysis of CD30 cells *in vitro* induced by an F_v construct of the invention versus lysis of CD30 cells *in vitro* induced by bimAbHRS-3/A9 is clearly displayed in Example 3(B) of the specification. In that example, the steps for performing a JAM cytotoxicity test utilizing an F_v construct of the invention are clearly set out. Such test allows for the detection of activation of NK cells and lysis of CD30⁺ L540CY Hodgkin's disease cells.

Reasonable appraisal of one of skill in the art

MPEP §2173.05(b) (“Relative Terminology”) states in the first heading of such section:

“WHEN A TERM OF DEGREE IS PRESENT,
DETERMINE WHETHER A STANDARD IS
DISCLOSED OR WHETHER ONE OF ORDINARY
SKILL IN THE ART WOULD BE APPRISED OF THE
SCOPE OF THE CLAIM”

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More specifically, the language of the section states that “[w]hen a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree....” Clearly, as set forth above, the claim and the specification set forth guidance that “a more intense lysis” is lysis of CD30 cells *in vitro* induced by an F_v construct of the invention versus lysis of CD30 cells *in vitro* induced by bimAbHRS-3/A9.

MPEP §2173.05(b) continues, stating that “[i]f...[the specification] does not [provide a standard for measuring the degree], a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention.”

As set forth above, both the claim itself and the language of the specification do provide a standard for measuring the degree of “a more intense lysis.” However, Example 3(B) of the specification sets forth a method (see, for example, the page 10, lines 24-27 of the specification) by which a skilled person is easily able to compare the lytic activity of a F_v construct of the invention with that of the bimAbHRS-3/A9 antibody. Both the F_v construct of claim 1 (through the teachings of the invention) and the bimAbHRS-3/A9 antibody (as DSM ACC2142) are readily available to one of ordinary skill in the art. Such comparison allows a determination of whether the F_v construct has a higher or lower lytic activity compared with that of the bimAbHRS-3/A9 antibody. Such determination is readily made by the JAM test of Example 3 and does not constitute an undue burden on one of ordinary skill in the art.

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Accordingly, claim 22 is clear and definite on its face and therefore particularly points out and distinctly claims the F_v antibody construct claimed therein. Accordingly, reversal of the final rejection of claim 22 under 35 U.S.C. § 112, second paragraph is requested.

(b) Claim 22 is enabled under 35 U.S.C. § 112, first paragraph

In the Final Office Action mailed August 24, 2006, the examiner further rejected claim 22 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement of that section. Specifically it is contended in the Office Action that bimAbHRS-3/A9 may not be known and readily available to the public. Applicants disagree.

The antibody bimAbHRS-3/A9 (DSM ACC 2142) is the subject matter of US 5,643,759 (claim 1). Therefore, it is submitted that the USPTO already has acknowledged the fulfillment of the deposit requirements under §112 in connection with the bimAbHRS-3/A9 antibody, in particular that the deposited antibody is freely accessible. The antibody is freely accessible from the DSM depository as DSM ACC 2142.

In the Advisory Action mailed November 7, 2006, the examiner alleged that a deposit made under the Budapest Treaty still may not meet all the requirements of "known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules." (Advisory Action mailed November 7, 2006, "Continuation Sheet.") Furthermore, the examiner alleges that U.S. Patent No.

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5,643,759 has expired due to non payment of maintenance fees and therefore “it is not clear if the antibody bimAbHRS-3/A9 (DSM ACC 2142 is readily available to the public or obtainable by a repeatable method...” (Advisory Action mailed November 7, 2006, “Continuation Sheet.”)

In the response submitted January 24, 2007, applicants submitted copies of (1) the deposit certificate obtained when bimAbHRS-3/A9 was deposited with the DSMZ and (2) the declaration of availability regarding bimAbHRS-3/A9 that was made in U.S. Patent No. 5,643,759. The response submitted January 24, 2007 by applicants was not entered by the examiner. Accordingly, the bimAbHRS-3/A9 deposit certificate and declaration of availability are not attached to this Appeal Brief. However, the declaration of availability is available to the public on PAIR on the U.S. Patent and Trademark Office website at <http://portal.uspto.gov/external/portal/!ut/p/.s.7.0.A/7.0.CH/cmd/ad/.ar/sa.getBib/.ps/N/.c/6.0.69/.ce/7.0.3AB/.p/5.0.341/.d/1?selectedTab=ifwtab&isSubmitted=isSubmitted&dosnum=08327254> as the document titled “Rule 130, 131 or 132 Affidavits” submitted on July 8, 1996 in prosecution of U.S. Patent No. 5,643,759.

The deposit of bimAbHRS-3/A9 was made in accordance with the requirements of the Budapest Treaty on August 6, 1993. The Declaration of Availability made in U.S. Patent No. 5,643,759 states in paragraph 3 that “upon allowance and issuance of the above-named application [08/327,254] as a United States Patent, all restriction on availability of the deposits designated in paragraph 1 hereinabove [including bimAbHRS-3/A9] will be irrevocably removed.” U.S. Patent Application No. 08/327,254 issued as U.S. Patent No. 5,643,759 on July 1, 1997. Therefore, the deposit of bimAbHRS-3/A9

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will be accessible, available, and obtainable at least until 2023, 30 years from the date of deposit.

As bimAbHRS-3/A9 is both known and readily available to the public until at least 2023, claim 22 is enabled under 35 U.S.C. § 112, first paragraph. Accordingly, reversal of the final rejection of claim 22 under 35 U.S.C. § 112, second paragraph is requested.

(c) **Claims 1-5, and 15 are patentable under 35 U.S.C. §102(b) in view of Hartmann et al., *Blood*, 89; 6:2042-2047 (1997).**

In the Final Office Action mailed August 24, 2006, the examiner rejected claims 1-5 and 15 under 35 U.S.C. §102(b) as being anticipated by Hartmann et al., *Blood*, 89; 6:2042-2047 (1997); hereinafter “Hartmann et al. 1997.” In particular, the examiner relied upon the reasons of record, that “Hartmann et al. teach an anti-CD16/CD30 bispecific antibody binds one arm to CD30, which is expressed on Hodgkin, and Reed-Sternberg cells and its second arm binds to CD16 on NK cells and is able to induce specific types of lysis of CD30 positive tumor cells.” (Office Action mailed March 13, 2006, p. 8.) And that “the side effects such as HAMAs in the anti-CD16/CD30 bispecific antibody treatment can be resolved by using less immunogenic bispecific single chain antibody or diabodies.” (Office Action mailed March 13, 2006, p. 8.) Applicants disagree that the teachings of Hartmann et al. 1997 teach the claimed invention.

Anticipation of a claim requires the disclosure in a single prior art reference of each element of the claim under consideration. (In re Spada, 15 USPQ2d 1655 (Fed. Cir., 1990), In re Bond, 15 USPQ2d 1566 (Fed. Cir., 1990). Claim 1, as appealed recites: “A

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F_v antibody construct having variable domains for CD16 and a CD30 but no constant domains and inducing a regression of Hodgkin's disease *in vivo*." Hartmann et al. 1997 do not teach all elements of the claimed invention. In particular, Hartmann et al. 1997 does not teach the combination of F_v constructs with no constant region and with dual specificity for CD16 and CD30.

In Hartmann et al. 1997, the reference to single chain antibodies or diabodies is found in the paragraph bridging the left and the right column on page 2046. This paragraph relates to a general discussion of side effects connected with "a BiMoAb therapy" (emphasis added). The authors merely hypothesize that F_v constructs could overcome side effects connected with monoclonal antibody therapy. However, this discussion about the use of the genus of diabodies does not anticipate a distinct species of F_v constructs having anti-CD16/CD30 specificities. The Hartmann et al. 1997 reference refers only to bispecific antibodies of the IgG type. The generic reference on page 2046 to single-chain antibodies for resolving problems associated with a generic monoclonal antibody therapy does not in any way contemplate the specifically claimed species of applicants' invention.

As Hartmann et al. 1997 does not describe an F_v antibody construct having variable domains for CD16 and a CD30 but no constant domains and inducing a regression of Hodgkin's disease *in vivo* as set forth in claim 1, Hartmann et al. 1997 does not anticipate the claimed invention. Claims 2-5 and 15 are dependent from claim 1 and therefore contain all the limitations of claim 1. As claim 1 is not anticipated by Hartmann et al. 1997, claims 2-5 and 15 are also not anticipated by Hartmann et al. 1997.

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Accordingly, reversal of the final rejection of claims 1-5 and 15 under 35 U.S.C. § 102(b) as being anticipated by Hartmann et al. 1997 is respectfully requested.

- (d) **Claims 1-6, 15, 19 and 22 are patentable under 35 U.S.C. §103(a) over Hartmann et al., *Leukemia and Lymphoma*, 31:385-392 (1998), in view of Hollinger et al., *PNAS*, 93:6444-6448 (1993).**

In the Final Office Action mailed August 24, 2006, claims 1-6, 15, 19 and 22 were finally rejected under 35 U.S.C. § 103(a) as obvious over Hartmann et al., *Leukemia and Lymphoma*, 31:385-392 (1998) (hereinafter "Hartmann et al. 1998") in view of Hollinger et al., *PNAS*, 93:6444-6448 (1993) (hereinafter "Hollinger et al.") This rejection has been maintained in the Advisory Actions mailed November 7, 2006 and February 6, 2007.

It is elemental law that in order for an invention to be obvious, the difference between the subject matter of the application and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art. In order to meet this standard for a proper §103 rejection, all claim limitations must be taught or suggested by the cited combination of references and there must be a motivation to combine the cited references and there must be a reasonable expectation of success in such combination. See MPEP §2143:

"2143 Basic Requirements of a Prima Facie Case of Obviousness

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation

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of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

“The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).”

Hartmann et al. 1998 in view of Hollinger et al. fail to teach or suggest all of the limitations of the claimed invention and, additionally, there would have been no motivation for one of skill in the art to combine such references. Accordingly, no basis of *prima facie* obviousness of appellants' claimed invention is presented by such cited references.

In light of the cited references, it would not have been obvious at the time of the invention that a bispecific F_v construct would be capable of inducing a regression of Hodgkin's disease *in vivo*, as claimed in claim 1 and claims 2-6, 15, 19 and 22 dependent therefrom.

Hartmann et al. 1998 specifically teach the use of anti-CD16/CD30 IgG antibodies for immunotherapy. Hartmann et al. 1998 do not teach or in any way suggest switching to any other antibody format for immunotherapy.

While Holliger et al. teach that antibody fragments may be preferable with regard to avoiding side effects caused by the F_c region of IgG antibodies and associated with the unwanted targeting to cells expressing F_c receptors, Holliger et al. do not teach or suggest

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that a bispecific F_v construct would have been capable of inducing a regression of Hodgkin's disease *in vivo*.

Holliger et al. merely teach that bispecific F_v diabodies bind to the respective antigen *in vitro*. However, Holliger et al. do not teach or indicate any cytotoxic or tumoricidal activity of the F_v constructs. Therefore, at the time of the invention, one of skill in the art could not have derived from Holliger et al. whether F_v constructs could exhibit a cytotoxic or tumoricidal activity *in vivo*. Holliger et al. do not contain any indication whatsoever about any cytotoxic *in vivo* activity. Thus, a skilled person considering the teaching of Holliger et al. would not have had a reasonable expectation of success (or, for that matter, any basis for any expectation of success) that a F_v construct could induce a regression of Hodgkin's disease *in vivo*. Therefore, one of skill in the art would not have been motivated to combine the Hartmann et al. 1998 and Holliger et al. references.

Additionally, the diabodies (approx. 60kD) of Holliger et al. are smaller than and structurally different from the IgG antibodies (approx. 150kD) of Hartmann et al. 1998. At the time the invention was made it was not known in the art that a diabody according to the teaching of Holliger et al. had any capability of immune recruitment by targeting and activating natural killer cells *in vivo*. As Holliger et al. lack a teaching of a cytotoxic or tumoricidal activity of the F_v constructs, a skilled person would not have been motivated to utilize the diabodies of Holliger et al., in place of the IgG antibodies of Hartmann et al. 1998 because it could not have been extrapolated from the *in vitro* binding affinity data of Holliger et al. with any reasonable expectation of success that F_v

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constructs of anti-CD16/CD30 specificity are capable of inducing a regression of Hodgkin's disease *in vivo*.

Therefore, claims 1-6, 15, 19 and 22, reciting a F_v antibody construct having variable domains for CD16 and CD30 that induces a regression of Hodgkin's disease *in vivo*, find no derivative basis in Hartmann et al. 1998 in view of Holliger et al.

Hartmann et al. 1998 in view of Hollinger et al. do not describe an F_v antibody construct having variable domains for CD16 and a CD30 but no constant domains and inducing a regression of Hodgkin's disease *in vivo* as set forth in claim 1, Hartmann et al. 1997 do not make the invention of claim 1 obvious. As claims 2-6, 15, 19 and 22 are directly or indirectly dependent from claim 1, all contain all the limitations of claim 1. As claim 1 is not obvious over Hartmann et al. 1998 in view of Hollinger et al., claims 2-6, 15, 19 and 22 are also not obvious over Hartmann et al. 1998 in view of Hollinger et al. Accordingly, reversal of the final rejection of claims 1-6, 15, 19 and 22 under 35 U.S.C. § 103(a) as obvious over Hartmann et al. 1998 in view of Hollinger et al. is respectfully requested.

CONCLUSION

For the reasons presented above, the rejections of claim 22 under 35 U.S.C. § 112, second paragraph, claim 22 under 35 U.S.C. § 112, first paragraph, claims 1-5, and 15 under 35 U.S.C. §102(b), and claims 1-6, 15, 19 and 22 under 35 U.S.C. §103(a) should be reversed.

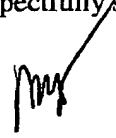
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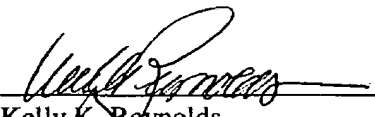
Enclosed with this appeal brief is a Credit Card Payment Form PTO-2038 authorizing the amount of \$250.00 for payment of the fee applicable to a small entity for filing a brief in support of an appeal, pursuant to 37 C.F.R. §§ 1.27(a) and 41.20. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account 08-3284 of Intellectual Property/Technology Law.

Respectfully submitted,

Date: 3/23/07


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Enclosures:
Claims Appendix [2 pgs.]
Evidence Appendix [1 pg.]
Related Proceedings Appendix [1 pg.]
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The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284

CLAIMS APPENDIX

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The claims pending and involved in this appeal are claims 1-6, 15, 19 and 22. While claims 7-14, 16-18, and 20-21 remain pending in this application, those claims are withdrawn and not involved in the appeal.

1. (Previously presented) A F_v antibody construct having variable domains for CD16 and a CD30 but no constant domains and inducing a regression of Hodgkin's disease *in vivo*.
2. (Previously presented) The F_v antibody construct according to claim 1, wherein the CD16 is derived from natural killer cells (NK cells).
3. (Previously presented) The F_v antibody construct according to claim 1, wherein the CD30 is derived from a member selected from the group consisting of: Hodgkin's disease or Reed-Sternberg cells.
4. (Previously presented) The F_v antibody construct according to claim 1, wherein one binding site is present each.
5. (Previously presented) The F_v antibody construct according to claim 4, encoded by the expression vector pKID16-30 (DSM 12960).
6. (Previously presented) The F_v antibody construct according to claim 1, wherein two binding sites are present for each.

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15. (Previously presented) The F_v antibody construct according to claim 2, wherein the CD30 is derived from a member selected from the group consisting of: Hodgkin's disease or Reed-Sternberg cells.
19. (Previously presented) The F_v construct of claim 1, wherein said F_v antibody construct comprises elements (a) and (b) joined via a peptide linker:
- (a) a VH domain of an anti-CD16 antibody and a VL domain of an anti-CD30 antibody, the domains being joined by a peptide linker; and
 - (b) a VH domain of an anti-CD30 antibody and a VL domain of an anti-CD16 antibody, the domains joined by a peptide linker.
22. (Previously presented) The F_v antibody construct according to claim 1, wherein said F_v antibody is capable of inducing a more intense lysis of CD30 carrying cells *in vitro* than bimAbHRS-3/A9 (DSM ACC2142).

EVIDENCE APPENDIX

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No evidence has been submitted pursuant to 37 CFR §§ 1.130, 1.131, or 1.132 in the application that is the subject of the present appeal, and appellant is not relying on any evidence by the examiner in the record. Accordingly, no evidence is identified in this Evidence Appendix.

RELATED PROCEEDINGS APPENDIX

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There exist no other prior or pending appeals, interferences or judicial proceedings known to appellant, appellant's attorney, or the assignee which may be related to, direct affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Accordingly, there exist no decisions rendered by a court or the Board in any related proceeding, such that no related proceedings are identified in this Related Proceedings Appendix.